REMARKS

STATUS OF THE CLAIMS.

Claims 45-70 and 74-76 are pending with entry of this amendment, claims 71-73 and 77-86 being canceled herein. Claims 45-67 are allowed. Claim 68 is amended herein. These amendments introduce no new matter.

RESTRICTION/ELECTION.

Pursuant to a restriction/election requirement, Applicants cancel claims 71-73 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and that the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

35 U.S.C. §102.

Claims 68, 69, 71, and 74 under 35 U.S.C. § 102 as allegedly anticipated by Tsuda et al. (Cancer Research (1989) 49:3104-3108). Office Action, page 1. This rejection moot as to canceled claim 71 and is respectfully traversed with respect to claim 68, 69, and 74,

Of the rejected claims, only claim 68 is independent. Claim 68 relates to a "method for detecting a copy number variation in a suspected breast cancer sample by detecting an amplification of unique sequences at "position q22 to about position q24" on chromosome 17. Detection is carried out by hybridizing a suitable probe to the sample and detecting the hybridization complex.

The Examiner states: "Tsuda teaches [a] method for detecting a copy number variation in a suspected breast cancer sample . . . by detecting an amplification or gain of unique sequences . . . on chromosome 17, about position q22 to about position q24." Office Action, pages 1-2. More specifically, the Examiner believes that Tsuda teaches the region "about position q22 to about position q24" because, according to the Examiner, Tsuda teaches that amplification "'of c-erbB2 was confirmed to be a factor indicating a poorer prognosis in breast carcinoma patients', also see figure 1, case A, where earl at position 17q21-22 is amplified." *Id.* The Examiner also

cites page 3104, column 2, which states that "c-erbB-2 and one of the v-erbA-related genes, ear-1 are localized on chromosomes 17q21 and 17q21-22, respectively." *Id.*

In the previous Amendment (dated November 12, 2003), Applicants stated "c-erbB-2 is actually located at 17q12, as indicated in Applicants' specification (page 26, line 22)." Amendment dated 11/12/03, page 13. In support of this statement, Applicants submitted a copy of a PDF file downloaded from the UCSC Genome Browser as Exhibit A, which indicated that c-erbB-2 is at 17q12, not 17q21.

The Examiner challenges this statement on the ground that "the NCBI report on Erbb2 places the gene at both 17q11.2 and 17q21.1." Office Action, page 4. The NCBI report for ErbB-2 contains the following information: "Genomic context: chromosome:17; Maps: 17q11-q12; 17q21.1." As Applicants indicated in the previous Amendment, there has been confusion in the scientific literature over the location of c-erB-2, which is presumably why the NCBI report refers to 17q21.1. However, this confusion has no bearing on claim 68 as this claim recites the detection of an amplification at the chromosomal region "on chromosome 17, position q22 to about position q24." This region clearly excludes the locus at 17q21.1, regardless of whether that locus is c-erbB-2 or something else.

A second gene that Tsuda disclosed as being amplified in breast cancer is ear-1, which Tsuda stated is at 17q21-q22. To be more precise, ear-1 is located at 17q21.1, as evidenced by Exhibits B and C, which accompanied the previous Amendment. Applicants submit that "17q22 to about 17q24" clearly distinguishes "17q21.1." As Tsuda fails to teach this element of claim 68, Tsuda does not anticipate the claimed method. Claims 69 and 74 depend from claim 68 and are therefore novel over Tsuda for at least the same reason.

35 U.S.C. §103(A).

Claims 70, 75, and 76 were rejected under 35 U.S.C. § 103(a) as allegedly obvious in light of Tsuda in view of Mullis *et al.* (U.S. Patent No. 4,683,202) Office Action, page 3. This rejection is respectfully traversed.

Claims 70, 75, and 76 depend from claim 68 and therefore incorporate the element of detecting an amplification at 17q22 to about 17q24. The Examiner contends that Tsuda teaches the detection of amplifications in this region. However, as pointed out above, Tsuda teaches amplifications at 17q12 (or possibly 17q11.2) and 17q21.1, not at 17q22 to about 17q24.

Mullis does nothing to remedy this deficiency. Mullis is cited as teaching the elements recited in claims 70, 75, and 76, namely labeling the sample nucleic acid (claim 70), using amplified DNA as the sample nucleic acid (claim 75), and using cDNA as the sample nucleic acid (claim 76). *See* Office Action, page 3. Mullis neither teaches nor suggests anything about detecting a copy number variation in a suspected breast cancer sample by detecting an amplification of unique sequences at "on chromosome 17, position q22 to about position q24," as recited in claim 68 and incorporated into dependent claims 70, 75, and 76. Thus, the Tsuda-Mullis combination fails to teach or suggest all of the elements of rejected claims 70, 75, and 76. Withdrawal of the § 103 rejection of these claims over Tsuda and Mullis is therefore respectfully requested.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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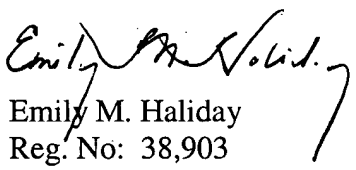
Respectfully submitted,



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